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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,221	10/16/2001	John Edward Norris Morten	P 0283779 100 203/US	3667

26161 7590 12/17/2002

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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	7

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/977,221	Applicant(s) MORTEN, JOHN EDWARD NORRIS
	Examiner Juliet C Einsmann	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to method for the diagnosis of a polymorphism in P2X7 and a method for assessing the pharmacogenetics of a drug, classified in class 435, subclass 6.

II. Claims 3, 4, 5, 6, 11, and 13, drawn to isolated nucleic acids which comprise polymorphic sites, classified in class 536, subclass 23.1, for example.

III. Claims 1 and 7, drawn to a method for the diagnosis of a polymorphism in P2X7 and the use of a P2X7 gene as a genetic marker in a linkage study, classified in class 435, subclass 6.

IV. Claims 1 and 8, drawn to a method for the diagnosis of a polymorphism in P2X7 and a method of treatment of a disease which encompasses a method of diagnosis of a polymorphism, classified in class 424, subclass 94.1.

V. Claim 9 and 12, drawn to an allelic variant of a human P2X7 polypeptide, classified in class 530, subclass 350.

VI. Claims 10, drawn to an antibody specific for an allelic variant of P2X7, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, inventions II and III, and inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention II can be used in a variety of methods, as is evident by the methods recited herein where the nucleic acids would be useful. Additionally, the nucleic acids of invention II can be used to express the encoded polypeptide, in amplification assays, and in nucleic acid purification assays.

3. Inventions I, III, and IV are drawn to distinct methods which have different goals and modes of operations. The methods share a common step wherein they utilize the method of diagnosing a polymorphism as set forth in claim 1, and so, claim 1 has been included in each group and will be examined with whichever method is elected, if one of groups I, III, or IV is elected. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion.

4. The methods of inventions I, III and IV are unrelated to the products of inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the polypeptides and antibodies of inventions V and VI are not disclosed as being used in or necessary for the methods of inventions I, III, and IV.

5. The products of groups II, V, and VI are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of Group II are composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix.

The polypeptides of Group V are composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibodies of group VI are also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of groups II, V, and VI can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group VI can be used in immunoassay, the polypeptide of Group V can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups II, V, and VI are patentably distinct from each other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

FURTHER RESTRICTION REQUIREMENT

7. A further restriction requirement is set forth for each group. Upon election of one of groups I-VI above, applicant is required to make a further election as set forth in the following paragraphs. Portions of MPEP 803.04 are repeated herein for Applicant's convenience.

> "Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 et seq. (and the partial waiver of 37 CFR 1.475 and 1.499 et seq., see MPEP § 1850) include...C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000...Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example (C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. ...The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed."

The claims differ from those discussed in MPEP 803.04 in a number of significant ways, one being that the sequences discussed in MPEP 803.04 are isolated DNA fragments whereas the instant claims are drawn to methods and products which utilize and comprise DNA polymorphisms.

A further restriction requirement is applied to groups I, III, and IV in the spirit of MPEP 803.04. The claims recite methods in which "one or more polymorphisms" from 43 different polymorphisms (some in nucleic acids and some in polypeptides) is identified. A search and examination for each individual method and each combination of methods would pose a substantial burden on the examiner and PTO resources because each individual method would require a separate search. There is not uniformity in the art with regard to the reporting of single nucleotide polymorphisms, nor are there available comprehensive databases that contain relevant information. In light of this burden, Applicant is required to select a single combination of polymorphisms to be examined during prosecution. Upon the finding of an allowable combination, combinations which comprise the allowable combination will also be rejoined and allowed.

For group II, which contains a multitude of nucleic acids, applicant is required elect a single allelic variant, corresponding primers and probes, and a single haplotype for claims 11 and

13. For groups V and VI, applicant is required to elect a single haplotype. Each of the probes to particular sections of the P2X7 gene and each of the haplotypes are distinct nucleic acid molecules with separate structures and functions. Even in cases where the polymorphisms do not result in coding changes, the possible effects on the activity of the nucleic acids are separate and distinct. A search and examination of all of the different nucleic acids and haplotypes set forth by applicant would pose a significant burden on the examiner and on PTO search resources because the search and examination would require separate consideration of each possible variant set forth in the claims, for prior art and for issues under 112 1st paragraph and 101. Therefore, the further restriction requirement is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

December 14, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600